K011752

6/28/01

DESCRIPTION OF THE GOVAN+ WHEELCHAIR

Designed to remedy perceived shortfalls in the design of standard wheelchairs, particularly in the category of user safety, the GOVAN+ device's distinctive appearance confirms that it is not meant to be a duplicate of the predicate device.

SUBSTANTIAL EQUIVALENCE IMPERATIVE

It has nonetheless been a constant imperative in the design of the GOVAN+ wheelchair to replicate the features of a standard wheelchair such as the predicate device. A comparison of the GOVAN+ device in its raised seating mode to the specifications of the Tracer EX confirms that this has been achieved. See comparison table on page 169.

INTENDED USE

Intended use of the GOVAN+ device (see Indications for Use on page 170) parallels usage of the predicate device. More on this in a moment, regarding use in vehicles.

NEW TECHNOLOGY

As might be expected with a new design, the GOVAN+ device incorporates technological characteristics that improve on those of the predicate device and result in a capacity to do the same things even better:

- Lower centre of gravity makes the GOVAN+ device much less prone to tip over - a real safety advantage. Tipping doesn't begin until 22° left or right; 27° posterior, 20° anterior; with occupant aboard.
- An ergonomically contoured, deeply padded automotive type seat provides more comfort for the user, especially one who has to sit in the wheelchair for long periods.
- Extensive postural adjustments are convenient to make when change of position is desired.
- The "normal" and handsome appearance of the device makes wheelchair users feel good about themselves, helps reduce the stigma of disability.

These technological features actually reinforce substantial equivalence, providing added safety and effectiveness to the equation, while retaining the original values of the predicate device.

MOBILITY DEVICES IN VEHICLES

In the real world, there is a massive safety issue in the use of the predicate device and other standard wheelchairs like it to transport disabled people in motor vehicles. Despite disclaimers in owner's manuals saying these devices are not to be used to carry persons in vehicles, it is common practice, and it is dangerous. Crash tests of such devices show what can happen, and it is not pleasant.

The GOVAN+ device, explicitly designed to resolve this problem, has been crash-tested repeatedly and meets or exceeds the dynamic test requirements of Section 19 ANSI/RESNA WC Vol.1. See page 171 for a digest of confirming data from the UMTRI test facility at University of Michigan, Ann Arbor.

So any vehicle with a compliant 4-point strap tie-down setup - and a lot of them have it - can carry the GOVAN+ device with the occupant aboard and be fully compliant. Every GOVAN+ wheelchair has 4 strap anchor points integral.

The GOVAN+ docking plate accessory provides users of the GOVAN+ wheelchair with a much more convenient alternative to the 4-point strap system if desired. Tested in combination with the GOVAN+ wheelchair this Docking System meets or exceeds the requirements of SAE J2249, the applicable docking/tie-down standard. See page 172 for a digest of confirming data from the UMTRI test facility of University of Michigan, Ann Arbor.

The combination of the GOVAN+ wheelchair and its docking accessory plate, because of its low profile in transit mode, enables even the family minivan without structural modification to carry a disabled person in a wheelchair and be fully compliant.

SUBSTANTIALLY EQUIVALENT?
INDEED IT IS. AND MUCH MORE.

In use outside a vehicle, with the seat raised, the GOVAN+ device in comparison with the predicate device is remarkably similar in standard Specifications and Indications for Use, yet provides an added measure of safety and effectiveness.

The commonplace use of the predicate device in vehicles is positively dangerous, whereas the GOVAN+ device is eminently safe and effective there, having met or exceeded the ANSI/RESNA STANDARD.

So across the whole spectrum, GOVAN+ matches or exceeds the predicate device at its own game, especially in the key characteristics of safety and effectiveness, to achieve substantial equivalence plus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Don Logan
President
Accufast, Inc.
251 Cree Crescent
Winnepeg, Manitoba, Canada R3J 3X4

JUN 2 8 2001

Re: K011752
Trade Name:
Regulation Number: 890.3850
Regulatory Class: I
Product Code: IOR
Dated: June 4, 2001
Received: June 6, 2001

Dear Mr. Logan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011752

Device Name: GOVAN+ Wheelchair and docking accessory

Indications For Use:

Therapeutic effect:

1) Provision of out-of-bed seating for disabled persons.

2) Transportation of disabled persons from one location to another in a room or in a building or outdoors.

3) Transportation of disabled persons in the device in motor vehicles.

Medical conditions for which the device is indicated:

1) Post-operative weakness or debility.

2) Age-related weakness or debility.

3) Paralysis due to stroke, tumour, etc.

4) Impairment of function due to MS, ALS, Polio.

5) Impairment from physical trauma.

6) Impairment from accidents at birth.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011752

Prescription Use ____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)